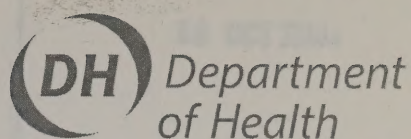


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# Research and Development for a First Class Service

R&D funding in the new NHS

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# Foreword

I am delighted to introduce this statement of policy and principles, and a development programme for NHS R&D Funding. They set out a series of changes that harmonise the reform of NHS R&D with the Government's modernisation programme for the NHS. They will:

- align the management and funding of R&D with the principles of *The new NHS*;
- **target NHS money** on the research priorities and needs of the NHS, and on providing the NHS base for **high quality science**;
- set a **strategic direction** for health services R&D for the benefit of the NHS;
- promote R&D **partnerships and networks** across the NHS and between the NHS, researchers and consumers, to meet the needs of health and health care;
- ensure consistent **governance** of R&D in the NHS; and
- strengthen **performance management** of NHS spending linked to R&D.

This country has an outstanding record of scientific innovation. In health, it rests on mutual support between the NHS, universities and bodies that fund high quality R&D. The reform of NHS R&D Funding strengthens this **partnership** to keep our research at the forefront of relevance, quality and value.

As well as providing solid support for the national science effort, the NHS must support R&D that is **relevant** to the national priorities of the NHS, **responsive** to the needs of those who use the NHS, its staff and decision-makers, and **accessible**. It must take an integrated approach to securing the knowledge we need if we are to tackle health inequalities and provide effective modern health and social care.

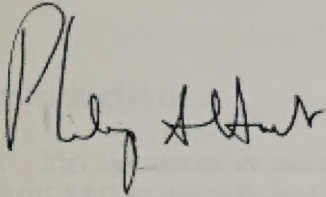
Programmes of R&D in the NHS should work within a **quality** framework of standards and systems to guarantee they:

- are of high scientific quality;
- are safe and ethical; and
- actively involve patients, carers and other consumers.

The public has a right to expect the same high standards of **cost-effectiveness** and accountability across all of NHS spending. These reforms will align the systems of management, performance management and costing for NHS R&D with those elsewhere in the NHS and with Government funding for research.



Since 1997, the NHS has made impressive progress in increasing the quality and relevance of the R&D it supports, and in involving consumers. It has also made a good start on improving transparency and accountability. For its part, R&D makes a substantial contribution to achieving better outcomes for patients. I intend to see that these efforts continue and I commend this statement of policy and principles to the NHS and its R&D partners.



Lord Hunt of Kings Heath  
Parliamentary Under Secretary of State for Health

Purpose and Principles

1.1. The purpose of this statement is to set out the principles that will guide the NHS in its research and development activities.

1.2. The NHS will ensure that its research and development activities are of high quality and relevance to patients.

1.3. The NHS will ensure that its research and development activities are transparent and accountable.

1.4. The NHS will ensure that its research and development activities are inclusive and involve patients.

1.5. The NHS will ensure that its research and development activities are of high quality and relevance to patients.

1.6. The NHS will ensure that its research and development activities are transparent and accountable.







# Executive summary

## Introduction

E1 This document sets the policy context and describes a development programme for the management of NHS R&D Funding in England. It is addressed to all who have an interest in R&D in and for the NHS, and reflects discussion with them.

## Policy

E2 The Government is committed to modernising the NHS. In order to improve health and tackle health inequalities it draws on the whole spectrum of health R&D pursued by the NHS itself and its R&D partners. It also works to promote science and technology transfer in order to improve health and wealth.

E3 The Government has a particular interest in promoting partnerships to maintain excellence in biomedical science and to deliver the benefits of this work. For basic and strategic research, the Department of Health contributes to the strategies of the research councils and meets the costs to the NHS of hosting their research. Similar arrangements pertain to the medical research charities. The Department itself takes the lead in public health and health services R&D, with valuable contributions from others.

## Purpose and Principles

E4 NHS R&D Funding provides resources:

- for R&D to meet the priorities and needs of the NHS; and
- to meet the NHS costs of hosting R&D supported by eligible external funders.

Treatment costs are generally met from patient care budgets.

E5 NHS R&D Funding is for work that contributes to public goals. Its use is planned in partnership between the Department of Health and the NHS, the universities and other research funders. Discussions between these organisations are held at national, regional and local level.

E6 Principles of corporate governance apply to NHS R&D Funding, in common with all public funds. In addition, the R&D activity it supports must observe the principles of research governance and be consistent with NHS bodies' statutory duty of quality and their responsibilities for clinical governance. Information on R&D activity and findings should be readily available.



## Organisation

E7 NHS R&D Funding will in future comprise:

- NHS Priorities and Needs R&D Funding; and
- NHS Support for Science.

Both systems will operate in harmony with the principles and practice of the new NHS and of Government support for science in general.

E8 NHS Priorities and Needs R&D Funding will support R&D required to underpin modernisation and quality improvement in the NHS. Priorities addressed will reflect the National Priorities Guidance, National Service Frameworks and the National Performance Assessment Framework, and the work of the National Institute for Clinical Excellence. NHS needs outside service priority areas will receive due attention and will reflect consultation with NHS users and staff.

E9 NHS Priorities and Needs R&D Funding will reflect the full range of NHS responsibilities for public health and health care in community, primary, secondary and tertiary settings. It will include:

- clinical R&D;
- R&D to develop and apply new technology in the NHS;
- health services R&D, including work on service delivery; and
- public health R&D, including epidemiology.

A key use of NHS Priorities and Needs R&D Funding will be to contribute to developing the capacity required to deliver the research needed by the NHS.

E10 NHS Priorities and Needs R&D Funding will support those best able to achieve the results required. These will include collaborations between the NHS, universities, local authorities and other bodies, and groupings outside institutional boundaries across clinical specialties, health communities and care pathways. The Department of Health may specify work in detail or agree a strategic direction within which those receiving funds have delegated authority to determine how best to deliver the desired results.

E11 NHS Support for Science will meet the NHS costs of supporting R&D under agreed standards of strategic direction and quality assurance by the research councils and other eligible R&D funding partners. It will include, where appropriate, an element for the costs of developing R&D proposals and for building work around that supported by the external funder.

## Development Programme

E12 The Development Programme is designed to achieve change whilst preserving stability in NHS bodies involved in R&D.

E13 Funding will be separated into NHS Support for Science and NHS Priorities and Needs R&D Funding from 2001/02 onwards, with systems to manage NHS Priorities and Needs Funding introduced in subsequent years. An R&D Modernisation Fund will help align funding with priorities over this period. Full details of the





operation of the new funding systems will be published in 2000, following consultation. Paragraphs 3.2 to 3.11 and Annex C describe the introduction of the new systems in detail.

E14 As the new funding systems are introduced, a quality framework for NHS R&D will be developed to improve leadership, systems to deliver results, and performance management.

E15 The Department of Health will take steps to improve leadership and strategic direction in public health and health services R&D in general, and in NHS Priorities and Needs R&D Funding in particular. It will publish a Departmental Science and Technology Strategy, and a cross-Government Public Health R&D Strategy in 2000. It will draw on expert advice that will focus initially on the areas of cancer, heart disease and stroke, and mental health, to build on the work of the Strategic Review of NHS R&D Funding.

E16 Work to improve leadership will also include the development, in collaboration with other R&D funders, of clearer standards for R&D governance, for the measurement of the outputs and outcomes of R&D, and for the work that the NHS and its R&D funding partners expect of one another. The Statement of Partnership between the NHS and external R&D funders will be revised. Universities will continue to be seen as key partners of the NHS in delivering high quality R&D.

E17 The Department will work with the NHS, universities and research funders to define and deliver the research capacity needed to meet the country's needs for public health, health services and clinical R&D. Specific initiatives to develop R&D in primary care and public health R&D will continue.

E18 Work on improving systems to deliver results will include the development of contracts and financial frameworks with clear statements of responsibility and accountability, particularly for R&D networks and collaborations. Responsibilities and length of contracts will vary, but the Department will aim to develop long-term agreements, subject to review, for programmes of work wherever this is appropriate.

E19 R&D staff in NHS Executive Regional Offices will lead communication of standards and priorities and support networking and sharing of best practice between NHS R&D directors and managers. There will be a drive to improve the quality of information to plan, conduct and account for health R&D, and to improve the quality of information on R&D findings.

E20 The new funding systems will include arrangements for reviewing the outputs, outcomes and value for money of the work they support. In addition, there will be a programme of performance management reviews to ensure that institutions are demonstrating leadership in R&D, have an understanding of the standards expected of them, and have adequate systems in place to drive up quality, ensure standards are achieved, and take corrective action where necessary.



# Part 1: Purpose and status of this document

1.1 This is a statement on behalf of the Secretary of State for Health. Its purpose is to set the policy context and outline a development programme for the allocation and management of NHS Research and Development Funding in England. It replaces *The Strategic Framework for the Use of the NHS R&D Levy (1997)*.

1.2 It is addressed to all who have an interest in the way NHS R&D Funding is used: the health service and its partners in R&D, and all those who could use or benefit from the outcomes of the work it supports.

1.3 In preparing this document, the Department of Health has sought assistance from those working in the National Health Service, the research community, academic organisations, the voluntary sector and industry. The NHS Consumers in R&D Group has contributed at each stage.

1.4 Part 2 of this document sets out the policy context for NHS R&D Funding and describes the purposes for which it may be spent and the principles underlying its allocation and management. It then explains how NHS R&D Funding will be organised into NHS Priorities and Needs R&D Funding, and NHS Support for Science.

1.5 Part 3 sets out a programme of work to modernise NHS R&D Funding and ensure that it is fully aligned with the policy and principles described in Part 2. It explains how the new funding systems will be established and how a quality framework for R&D will be developed to improve leadership, systems to deliver results, and performance management.

## Government policy on health and health care

The new NHS: Modern – Dependable	Cm 3809
Our Healthier Nation – Saving Lives	Cm 3852
A First Class Service: Quality in the new NHS	HSC 1998/113
Modernising Mental Health Services	HSC 1999/038
Modernising Health & Social Services: National Priorities Guidance 2000/01 – 2002/03	HSC 1999/242
Partnership in Action	Cm 3807

Command papers are published by HMSO, Health Service Circulars by Department of Health.





# Part 2: Policy, Principles and Organisation of NHS R&D Funding

## Research, Government Policy and the NHS

2.1 The Government works to improve the wealth, health and well being of the nation. It is committed to modernising the NHS and to improving the quality of the care it provides. Research is vital to these endeavours. Basic and strategic research underpins the development of new ways of promoting and protecting health and curing and caring for the sick. Applied research underpins improvements in the organisation, responsiveness, effectiveness and efficiency of services.

2.2 The Government also promotes science, technology and technology transfer to improve the competitiveness of industry and the quality of public services. It wishes to maintain and improve the UK's international standing in science in general and biomedical science in particular. To this end, it seeks to promote the partnership within and between government, the NHS, the universities, industry and the voluntary sector that will allow health related research to prosper and ensure that the nation continues to reap the benefits to health and wealth that such work can bring.

### Triple Government support for R&D in the NHS in England

- Office of Science & Technology funds science through research councils
- Higher Education Funding Councils funds the academic base
- Department of Health funds the NHS base, and R&D for NHS priorities and needs

2.3 The NHS is engaged in a broad spectrum of health-related R&D. Some of this work is led by the Department of Health and the NHS itself, and some by their research partners in the research councils, the universities, the voluntary sector and industry.

2.4 For basic and strategic research, the Department of Health contributes to the strategies and priorities of the Medical Research Council and other research councils. It meets the costs to the NHS of providing access and support for high quality research led by these bodies. The medical research charities also make a vital contribution to the national science effort, and the Department therefore meets NHS costs associated with their work. The Department and the NHS supplement the work of the research councils and charities with further basic and strategic research in areas of particular relevance to their responsibilities.

2.5 For public health and health services R&D, the Department of Health takes the lead in defining and addressing the needs of the country and the NHS. The research councils and charities also make valuable contributions by funding work in these areas.



2.6 The NHS, research councils and charities all fund clinical research.

2.7 Industry is the largest funder of health-related R&D in the UK. Much of the R&D funded by industry is undertaken in commercial facilities, but much also involves the universities and the NHS. Government policy is that industry should meet the full costs of work that the NHS undertakes for industry under contract. The Department of Health and the NHS also engage in collaborative work with industry where both derive benefits and the costs are therefore shared.

## Purposes and Principles of NHS R&D Funding

### Purposes

2.8 NHS R&D Funding provides resources:

- for research to meet the priorities and needs of the NHS, particularly to provide knowledge for public health, clinical practice, and the provision of health and related social care; and
- to meet the costs of the NHS's involvement in health research under defined standards of strategic leadership and quality assurance provided by eligible R&D partners of the NHS.

#### Purposes of NHS R&D Funding

- Identify needs
- Evaluate R&D
- Address R&D priorities and needs of the NHS
- Secure involvement in partners' R&D
- NHS contribution to R&D infrastructure and environment
- Make findings accessible
- Encourage exploitation
- Evaluate implementation

2.9 NHS R&D Funding may therefore be used for revenue costs associated with the following activities:

- supporting the capacity of the NHS and others to **identify needs** for health and health services R&D, and to **evaluate** the value of this R&D;
- funding the whole range of R&D required to address the **priorities and needs** of the NHS;
- meeting specific costs of involvement in R&D led by the research councils, medical research charities and other eligible R&D funding **partners** of the NHS;
- meeting the costs of the NHS's contribution to the **infrastructure and environment** in which health related R&D and its methods can flourish, and be well managed – including helping to train researchers;
- contributing to ensuring that research **findings** are readily **accessible** to those working in and using the NHS;
- helping to encourage the **exploitation** of research findings; and
- evaluating techniques for **implementing** the findings of research.





2.10 R&D in the NHS may involve “research costs”, “service support costs” and “treatment costs”. NHS R&D Funding will normally cover service support costs of work led by R&D funding partners of the NHS, and research and service support costs of other work. Definitions of these costs and of how they are met can be found in Annex A.

2.11 Whatever purposes it may be serving, any use of NHS R&D Funding must adhere to the following principles.

#### Principles of NHS R&D Funding

- R&D for NHS and public goals
- Partnership
- High standards of governance
- Free access to information

### Pursuit of NHS and other public goals

2.12 NHS R&D Funding is taxpayers’ money voted by Parliament for the NHS. NHS R&D Funding is for work that will contribute to the goals of the NHS and its partners in health and social care, or to the Government’s goals for public support for science and technology.

### Partnership

2.13 The effective development and exploitation of R&D in and for the NHS calls for partnership between the Department of Health and the NHS, the research councils, the medical research charities, the universities and the Higher Education Funding Council for England (HEFCE).

2.14 At national and regional level, the Department of Health plans the use of NHS R&D Funding in discussion with these bodies. The Department expects these bodies similarly to discuss with it plans that may affect the location or nature of calls for NHS R&D Funding, or the provision of NHS services.

2.15 At local level, NHS bodies and their university partners should follow the principles and recommendations in the report on *Developing the Joint University/NHS Planning Culture*<sup>1</sup> from the joint Department of Health and Higher Education Funding Council for England Task Group.

### Governance

2.16 Recipients of NHS R&D Funding must manage it within the principles of corporate governance that apply to all public funds. They must have adequate systems to manage resources and activity that have a bearing on R&D, and effective systems of internal control.

2.17 R&D in the NHS must observe the principles of research governance:

- Consistent quality standards, appropriate to the methodology, should be applied. This will normally involve appropriate external peer review of the adequacy of protocols and R&D teams.

1 Higher Education Funding Council for England, 1999.



- Research activity must be consistent with NHS bodies' duty towards patients, and with their statutory duty of quality and responsibilities for clinical governance. All R&D in the NHS involving patients or patient information requires the approval of the appropriate research ethics committee(s), and should have adequate systems for securing consent and protecting confidential information.
- R&D in the NHS should be conducted with the active involvement of patients, carers and other consumers. Recipients of NHS R&D Funding are expected to show how they and their R&D partners pursue such partnership.

2.18 All recipients of NHS R&D Funding must account to the Department of Health for their performance in managing the funding and the activity it supports.

Free access to information

2.19 Information on R&D in and for the NHS should be shared for the benefit of the NHS, the research community and the public good. Recipients of NHS R&D Funding and R&D partners are expected to keep high quality records, and to collaborate with the Department of Health in maintaining, pooling and publishing comprehensive, timely and accurate records, both of the R&D that is supported by NHS R&D Funding and of its findings. Subject to the need to protect Intellectual Property Rights, R&D findings should be readily available, open to critical examination, and accessible to health care professionals, patients, carers and the wider public.

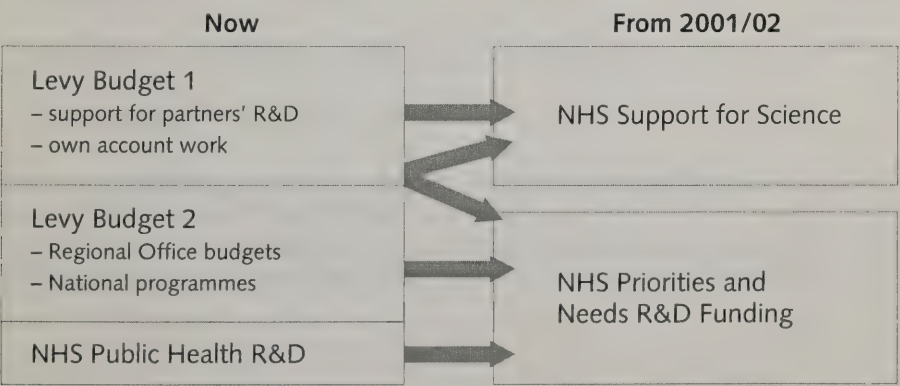
Organisation of NHS R&D Funding

2.20 NHS R&D Funding will be organised into two funding systems from April 2001 to reflect its two basic purposes. The two funding systems are:

- **NHS Support for Science;** and
- **NHS Priorities and Needs R&D Funding.**

2.21 This is a development of the current funding arrangements. The diagram below shows how the current components of NHS R&D Funding relate to the new systems.

Components of NHS R&D Funding







2.22 The Department will keep under review the two new funding systems, in the light of the principles and priorities set out in this document.

2.23 The Department will publish details of the operation of the two new systems on its website. They will operate in ways that are consistent with the principles and practice of *The new NHS*<sup>2</sup> and with the organisation of government funding for science.

## NHS Priorities and Needs R&D Funding

2.24 The Government puts quality at the top of the NHS agenda. NHS priorities and Needs Funding will support R&D that is needed – over and above that supported by other funders – to underpin modernisation and quality improvement in the services the NHS provides in its own right and in partnership with those working in public health and social care.

2.25 In allocating NHS Priorities and Needs R&D Funding, the Department will look for evidence first that work supported will lead to improvements in NHS care (in the short, medium or longer term), and second that NHS bodies receiving funding have appropriate systems to link R&D to clinical practice and organisational development, within the NHS Quality Framework described in *A First Class Service*<sup>3</sup>. The diagram at Annex B shows the relationship between health R&D, policy and practice, and how all those who use and work in the NHS – whether or not they are directly involved in undertaking R&D – can help to ensure that R&D is relevant to, and impacts upon, health and health care.

### NHS Priorities and Needs R&D Funding

responds to

- National Priorities Guidance
- National Service Frameworks
- National Performance Assessment Framework
- National Institute for Clinical Excellence
- Needs of the NHS

2.26 NHS Priorities and Needs R&D Funding will address:

- the implementation of the NHS priorities in National Priorities Guidance;
- the programme of National Service Frameworks and the National Performance Assessment Framework;
- the work of the National Institute for Clinical Excellence; and
- the needs of the NHS in implementing Government policy.

2.27 The Department will seek, and make available, expert advice on priorities for R&D to support these strands of work. The Department of Health will also consult with users of the NHS and with NHS staff to ascertain other needs that ought to be addressed, taking expert advice to clarify specific research issues and questions. R&D outside current national priority areas will continue to receive due consideration.

<sup>2</sup> House of Commons Paper 3809; London: HMSO, 1997.

<sup>3</sup> Health Services Circular 1998/113; London: Department of Health, 1998.



2.28 Each Health Authority in England is responsible for strategic planning to improve the health of its population and to determine what health care is needed in its area. NHS Priorities and Needs R&D Funding will include R&D relating to public health, epidemiology and service delivery as well as R&D into care in the community, primary, secondary and tertiary care settings.

2.29 NHS bodies, including those that host research, have a duty to co-operate with one another and with local authorities to secure and advance health and welfare. NHS Priorities and Needs R&D Funding will reflect this. It will fund those organisations and collaborations best able to achieve the objectives for a particular topic area. These may include, for example, a managed network in a clinical specialty, or an appropriate collaboration of the NHS with universities, local authorities or other bodies to which the Secretary of State for Health has powers to make payment. As well as work on topics related to particular disease or care groups it may cover R&D spanning, for example, a whole health community or care pathway.

#### **NHS Priorities and Needs R&D Funding**

embraces R&D for

- |                    |                                 |
|--------------------|---------------------------------|
| • Public health    | • Secondary care                |
| • Epidemiology     | • Tertiary care                 |
| • Service delivery | • Single disease or care groups |
| • Community care   | • Whole health communities      |
| • Primary care     | • Whole patient pathways        |

2.30 NHS Priorities and Needs R&D Funding will support:

- R&D activity commissioned by the Department of Health on behalf of the NHS as a whole; and
- Programmes of R&D work in NHS bodies and research institutions.

The Department may specify such R&D programmes in detail, or may agree a strategic direction for an appropriate body, collaboration or network that has delegated authority to determine how to deliver the desired results.

2.31 NHS Priorities and Needs Funding will support the full range of work that the NHS needs over and above that supported by its R&D funding partners, including:

- clinical R&D;
- R&D to develop and apply new technology in the NHS where there is no commercial sponsor;
- health services R&D; and
- public health R&D.

Methods will include systematic reviews and other secondary R&D, as well as primary R&D studies.

2.32 A key use of NHS Priorities and Needs R&D Funding will be to contribute to the national effort in developing and sustaining the capacity to undertake R&D in areas of importance to the NHS. The Department will work with the NHS and universities, other government departments and agencies, the research councils and the medical research charities to identify current and future needs for R&D skills and their potential configuration, and identify how the NHS and its partners can help to remedy shortages.



## NHS Support for Science

2.33 NHS Support for Science is available to NHS bodies and providers of NHS services to meet costs they incur in supporting R&D in the NHS under the direction and quality assurance of:

- an eligible R&D funding partner; or
- NHS Priorities and Needs R&D Funding.

2.34 Allocations from NHS Support for Science will reflect the different responsibilities and costs of managing R&D at NHS sites that collaborate in R&D led by others, and in those that take on the responsibilities of lead organisations for R&D at their own and other sites.

2.35 NHS Support for Science will include where appropriate an element to recognise the costs of preparing protocols to submit for external funding; for pilot work; and for associated R&D intended to underpin, strengthen and develop work funded by the eligible R&D funding partner(s).

### NHS Support for Science

- Is for any NHS body or provider of NHS services
- Meets NHS costs of NHS involvement with partners' R&D
- Recognises responsibilities of investigator site R&D
- May include pre-protocol work and associated R&D

2.36 Definitions of an eligible R&D funding partner and of the obligations of such partners and of the NHS are set out in the Statement of Partnership, available on the R&D pages of the Department of Health's web site.





# Part 3: Development Programme

## Introduction

3.1 This part of the document describes action that will be undertaken by the Department of Health and the NHS, involving their R&D partners as appropriate, to align NHS R&D Funding more closely with the policy and principles set out in Part 2. It will comprise work to:

- establish fair and transparent systems for NHS Support for Science and for NHS Priorities and Needs R&D Funding;
- improve leadership for relevance and quality;
- improve systems to deliver results for the NHS and for science; and
- improve performance management.

### A quality framework for NHS R&D

- |                                     |  |
|-------------------------------------|--|
| • Fair and transparent systems for: | • Leadership for relevance and quality |
| • NHS Priorities and Needs R&D      | • Systems to deliver results           |
| • NHS Support for Science           | • Better performance management        |

The work on leadership, delivery systems and performance management will define a quality framework for R&D.

## Establishing the new funding systems

3.2 From 2001/02 onwards NHS R&D Funding will be separated into NHS Support for Science and NHS Priorities and Needs R&D Funding. The steps that will be taken to achieve this are set out below. They are designed to achieve managed change whilst preserving stability in NHS bodies involved in R&D. Annex C provides a summary in chronological order.

3.3 The Department will publish draft proposals for the future operation of NHS Support for Science and of NHS Priorities and Needs R&D Funding in April and June 2000 respectively. Final details of the two systems, taking account of comments on the draft proposals, will be announced in October and December 2000 respectively.

3.4 The Department will establish an R&D Modernisation Fund to help to align funding with the priorities and configurations for NHS Priorities and Needs R&D Funding described in paragraphs 2.24 to 2.32.



**Establishing new systems**

- Change with stability
- Consultation on details
- NHS R&D Modernisation Fund
- Expert advice on NHS R&D priorities
- No bidding round
- Collaborative project on cost attribution
- Access for Health Authorities

**3.5 For NHS R&D Funding allocations for 2001/2002:**

- There will be no bidding. The Department will provide indicative allocations to existing contract holders in July 2000 having regard to strategic plans, annual R&D report(s) (where applicable) for 1999/2000 and 1998/1999, information from the National Research Register and from other research funders, and expert advice on NHS R&D priorities.
- In July 2000 NHS bodies will provide information about external grants from eligible R&D funding partners<sup>4</sup> that drive their NHS costs.
- The Department will conduct analyses of NHS activities and costs associated with a range of externally funded R&D in a number of NHS bodies. These studies will be conducted jointly with the NHS and external funders and will involve widespread consultation and discussion. The information from them, together with information from all NHS bodies on externally driven R&D, will be used to estimate the proportion of each body's indicative allocation that will in future be managed within NHS Support for Science, with the remainder to be managed within NHS Priorities and Needs R&D Funding. These estimates will be discussed with the bodies concerned in October. NHS Support for Science allocations will be announced in December 2000.
- The Department will aim to announce allocations for 2001/2002 from the R&D Modernisation Fund in October 2000. They will reflect expert advice and discussions with those parts of the NHS and university system best placed to respond to the top priorities identified for initial action.

3.6 Allocations of NHS Support for Science in 2002/2003 and subsequent years will reflect any material changes in the scale and location of reported eligible R&D in the NHS and its impact on NHS costs.

**3.7 For allocations of NHS Priorities and Needs R&D Funding in 2002/2003:**

- The Department will aim to announce indicative allocations by December 2000.
- The Department will announce allocations from the R&D Modernisation Fund by October 2001. Allocations will reflect: information from NHS bodies and their R&D partners about their work and plans in key areas; expert advice; and discussions with selected NHS bodies and universities.
- Main allocations will be confirmed by December 2001.

**3.8 For allocations of NHS Priorities and Needs R&D Funding in 2003/2004:**

- NHS bodies will be required to provide detailed information by March 2001 of all R&D work whose costs are not met by the NHS Support for Science allocation notified to them in December

<sup>4</sup> For the purposes of this exercise, eligible R&D funding partners will be as defined in the current Statement of Partnership, available on the R&D pages of the Department's website ([www.doh.gov.uk/research](http://www.doh.gov.uk/research)).





2000, and to indicate how they propose this work should be managed in the NHS Priorities and Needs R&D Funding System.

- The Department will announce in the summer of 2001 how all work supported by NHS Priorities and Needs R&D Funding, including that currently funded through the NHS R&D Programme, will in future be grouped, managed and reviewed over a five year cycle.
- The Department will establish initial reviews in this cycle, to report by the end of 2001.
- On the basis of these reviews and of expert advice on priorities and needs, the Department will announce early in 2002 allocations of NHS Priorities and Needs R&D Funding for 2003/2004.

3.9 Allocations of NHS Priorities and Needs R&D Funding from 2004/2005 will reflect the outcome of reviews and expert advice in 2003 and subsequent years.

3.10 The Department will work with the NHS in 2000 to explore the best way of integrating Health Authorities' current funding for R&D and R&D capacity with the new R&D funding systems. Health Authorities will be eligible, jointly with other NHS bodies, to receive NHS R&D Funding from 2001/2002.

3.11 The work described at paragraph 3.5 above is designed to establish a clear and consistent approach to costing NHS Support for Science, in harmony with the costing of other NHS activities. The development of costing for R&D in the NHS will take account of work which the Department is pursuing with the Office of Science and Technology within the Transparency Review of university funding to harmonise the principles of R&D costing in the NHS and universities. In the course of all this work the Department will consider and discuss with the NHS whether any further work is needed to simplify the costing of R&D, or to improve consistency in the costing of R&D, or to improve the consistency between the costing of R&D and other NHS activity.

## Improving leadership

Leadership

Department of Health will provide better leadership:

- Strategic direction
- Expert advice
- Standards
- Partnership with other research funders
- Partnership with universities
- R&D capacity

## Strategic direction

3.12 The Department of Health will provide leadership in applied public health and health services R&D by:

- publishing a Science and Technology Strategy in early 2001;
- publishing a cross-Government Public Health R&D Strategy in 2000, clarifying (amongst other things) the contributions of the NHS and its partners to public health R&D;
- giving strategic direction to work supported by NHS Priorities and Needs R&D Funding;
- expressing NHS priorities and needs for research in these areas in dialogue with its partners.



3.13 The strategic direction for NHS Support for Science is set by the eligible R&D funding partners of the NHS, with input from the Department of Health. Paragraphs 3.20 to 3.22 below describe how the Department will clarify and build on its understandings with these partners, including means by which it can influence their strategies and priorities.

3.14 The next section describes the steps that the Department will take to obtain expert advice to inform work to clarify the strategic direction of research in and for the NHS.

## Expert advice

3.15 The Department of Health will establish expert advisory structures to advise on R&D priorities and needs in particular topics and how these can best be addressed. These structures will address needs for R&D collaborations, capacity and infrastructure as well as specific projects and programmes of work. They will advise on needs in both the short and longer term. Initially, their advice will be used primarily to inform decisions about use of the R&D Modernisation Fund. Their advice will form a key part of the reviews of work within NHS Priorities and Needs R&D Funding once those are established.

3.16 Three NHS R&D advisory groups will be formed in 2000 to advise on cancer, heart disease and stroke, and mental health. These groups will build on the recent Strategic Review of NHS R&D Funding and in particular the work of the review's Topic Working Groups<sup>5</sup>. They will take due account of the needs of the elderly and children and the commitment to primary care R&D.

3.17 NHS R&D advisory groups on further topics will be announced in due course. The work of advisory groups will be co-ordinated with national service frameworks and other work to develop standards and guidance for the NHS in key areas.

## Standards

3.18 The Department of Health will work during 2000 with a range of R&D partners to clarify standards within a Framework for R&D Governance in Health and Social Care. Work on this began in 1999, building on existing guidance on the responsibilities of NHS bodies for good clinical practice in clinical trials. A draft Framework will be published in summer 2000 for testing with the NHS, universities and research funding bodies. A final version will follow, and performance management on this basis will begin in 2001/2002.

### Standards

- |                  |   |
|------------------|---|
| • R&D governance | • Timeliness and impact of outputs      |
| • Productivity   | • Evaluation of impact of new knowledge |

3.19 The Department will also develop standard approaches to the measurement of outputs and evaluation of outcomes. It will work with the NHS, universities and R&D funding bodies to develop:

- indicators of the productivity of NHS research capacity and funding;
- indicators of the timely delivery and impact of the outputs of specific projects and programmes receiving NHS R&D Funding; and
- approaches to periodic evaluation of the impact of more general advances in knowledge.

<sup>5</sup> The report of the Strategic Review and its Topic Working Groups on cancer, heart disease and stroke, mental health, ageing and primary care are available on the Department of Health's web site, together with a linked report on R&D priorities in relation to accident prevention.



Partnerships with other funders

3.20 The Department will develop its partnerships with R&D funding bodies to reach understandings about goals and standards that apply to all R&D activity in and for the NHS. It will:

- work with the main R&D funding bodies in 2000 to define initial standards of strategic direction, mutual influence, open access and quality assurance;
- develop joint mechanisms to discuss strategic direction, priorities, standards and processes at the working level;
- clarify the contributions of other R&D funders to supporting clinical, public health and health services R&D;
- build on the already close partnership set out in the Concordats with the research councils, to refine information sharing and joint planning;
- develop the Statement of Partnership with other research funding bodies into an agreement based on clear standards and mutual obligations; and
- enter into a formal Strategic Alliance with HEFCE.

Partnership	
• Strategic direction	• Open access
• Mutual influence	• Quality assurance

3.21 It will become a condition of eligibility for NHS Support for Science that research funding bodies have systems to apply these standards. During 2001/2002, the Department of Health will seek evidence of these systems, and provide guidance to the NHS on eligible R&D funding partners.

3.22 R&D funding bodies unable to demonstrate the standards expected for NHS Support for Science may continue to work with NHS bodies through joint funding of activities supported through NHS Priorities and Needs R&D Funding.

Partnership with universities

3.23 From April 2001, universities will not normally be treated as external R&D funding partners, but as partners of the NHS in delivering relevant, high quality R&D findings.

3.24 NHS Support for Science may cover the NHS costs of support for eligible R&D which university staff lead, collaborate in or support, provided these staff hold personal NHS contracts that define responsibilities in respect of the governance of R&D affecting NHS patients. The Department of Health will provide by December 2000 a standard form of words for the NHS to use in such contracts.

3.25 NHS Priorities and Needs R&D Funding will also rely on the collaborative partnership between NHS and Universities. Work involving university staff that is not under the strategic direction and quality assurance of an eligible external R&D funding partner will continue to attract NHS support provided it forms part of an agreed collaborative programme within NHS Priorities and Needs R&D Funding.





R&D capacity

3.26 The Department of Health will take the initiative in co-ordinating long term plans to secure the human resources and other capacity needed to meet the country's needs for public health and health services R&D. It will work with the NHS, universities, the research councils, HEFCE and other partners to define the R&D capacity the NHS needs and to harmonise and coordinate approaches to developing and sustaining this. Each appropriate funding agreement with an NHS body and/or university will include from April 2001 a standard requirement for a long term plan for developing and retaining key skills. The Department will also explore with CVCP, HEFCE, MRC, the research charities and the range of health care professions, robust ways of combining and promoting clinical and academic careers.

3.27 The Department will complete during 2000 its specific plans to develop academic capacity in public health. A key part of this will be schemes, developed in collaboration with the research councils and universities, to promote academic leadership and research capacity in public health.

3.28 The Department will also continue to develop R&D capacity in primary care in discussion with stakeholders. The Department will continue to support primary care research networks in their work to develop the capacity of primary care to identify the need for R&D, help carry it out, and make use of findings. Links with academic partners that provide R&D leadership and methodological support will be reinforced.

3.29 The new funding systems will be designed to be compatible with primary care structures and to minimise bureaucracy for those pursuing R&D in primary care. The Department will work with the Federation of Primary Care Networks and others during 2000 to agree core network and practice activities, and associated reference costs, that will be eligible for NHS Priority and Needs R&D Funding. It will also develop criteria along the lines of the Royal College of General Practitioners' research practice accreditation scheme to distinguish investigator and collaborating primary care sites for NHS Support for Science. The new systems will develop to engage Primary Care Trusts.

Improving systems to deliver results

Responsibilities, quality and accountability

3.30 The Department of Health will manage NHS Priorities and Needs R&D Funding jointly with the NHS and universities. As paragraph 2.30 indicates, the Department will, in some cases, take responsibility itself for identifying R&D needs and commissioning work to address them at the project level. In other cases, it will delegate these responsibilities to bodies that have demonstrated their ability effectively to manage research programmes or centres within a broader strategic remit.

**Systems to deliver results for the NHS and for science**

- Responsibilities
- Quality
- Accountability
- Communication
- Information

3.31 Paragraph 2.29 explains that NHS Priorities and Needs Funding will in some cases embrace groupings of NHS and other bodies and span professional networks across geographic boundaries. The Department will develop and consult on models for developing arrangements for such collaborations which promote integrated working whilst ensuring clear responsibilities and accountability.



3.32 In NHS Support for Science, the Department and the NHS are responsible for ensuring that R&D funding partners' work is supported efficiently in the NHS. The R&D funding partners are responsible for the strategic direction, value and scientific quality of the work supported.

3.33 The Department of Health will continue to set out the responsibilities of recipients of NHS R&D Funding in agreements brought together under an R&D financial framework. These agreements will be for a duration that suits the nature of the activity. The Department will prefer stable long term agreements that are subject to review and variation, but may also make fixed term, task-specific or ad hoc agreements. It will work with the NHS to develop forms of R&D financial framework for partnerships and networks framed around a joint R&D agenda.

3.34 Paragraph 3.18 describes work to develop and implement a Framework for R&D Governance in Health and Social care. The Department will work with the NHS to support the development and dissemination of best practice in management systems to drive up the quality of R&D and ensure compliance with standards. NHS bodies and their university partners will be expected to work collaboratively and to share systems where appropriate to achieve these high standards.

## Communication

3.35 NHS R&D directors and managers are a key resource in communicating research standards and priorities in the NHS, in developing and sharing best practice in research management, and in managing change. They will be encouraged to form a quality and learning network in 2000.

3.36 R&D staff at the regional offices of the NHS Executive will lead consistent communication of standards and priorities, and support networking and sharing of best practice.

## Information

3.37 The quality and relevance of R&D in and for the NHS depends on reliable, accessible information. There will be a drive to improve the quality of health and health service information needed to conduct health R&D, the quality of information needed to plan and account for NHS R&D Funding, and the quality of information on R&D findings.

3.38 The Department of Health will work with the NHS and its R&D partners within the framework set out in this document and in *Information for Health: An Information Strategy for the Modern NHS 1998-2005*<sup>6</sup> towards the following aims:

- improve the quality and coverage of routine data on health and health care, and its accessibility for public health and health services R&D, within the constraints of the law and ethical guidelines;
- clarify policy and practice for the support of other databases and registers;
- reduce fragmentation and duplication of R&D by collecting and sharing reliable information about current R&D;
- use high quality information about NHS needs and current R&D to identify priorities;
- improve accountability through public reporting of R&D costs and achievements;
- support evidence-based policy and practice by improving access to findings and evidence.

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6 London: Department of Health 1999.





### 3.39 In order to achieve the above:

- The Department will work with the NHS, universities and research funding bodies during 2000 to further improve the quality and completeness of the National Research Register and minimise the demands on data providers.
- From 2001/2002 it will be a condition of NHS Priorities and Needs R&D Funding that an annual report proportionate to the funding received is published on behalf of the relevant body, partnership or network. The report will describe: the outputs and the outcomes of the R&D undertaken, the human and financial resources applied to agreed priorities and action taken to maintain or achieve high standards.
- From 2001/2002 it will be a condition of NHS Priorities and Needs R&D Funding that those supported make findings accessible by contributing accurate and timely records to a publicly available Research Findings Register.

## Improving performance management

### 3.40 Performance management is essential for ensuring that recipients of NHS R&D Funding:

- are demonstrating leadership in R&D and an understanding of standards expected of their work in R&D;
- have adequate systems in place to drive up the quality of their R&D activity, ensure that standards are achieved, and take corrective action where necessary;
- are providing value for money in terms of the outputs and outcomes of the work for which they are receiving funding.

#### Performance management

Focused to demonstrate

- Leadership and standards
- Systems to drive up quality, maintain high standards
- Value for money from outputs and outcomes

3.41 Detailed arrangements for NHS Support for Science and NHS Priorities and Needs R&D Funding will be published in October and December 2000 respectively (see paragraph 3.3). These will define arrangements for reviewing funding allocated within each system. There will in addition, be arrangements for a programme of institutional reviews to work alongside reviews of specific funding allocations. Full details of the new performance management arrangements for R&D in the NHS will be published in December 2000, to take effect from 2001/2002.



# Costs associated with R&D

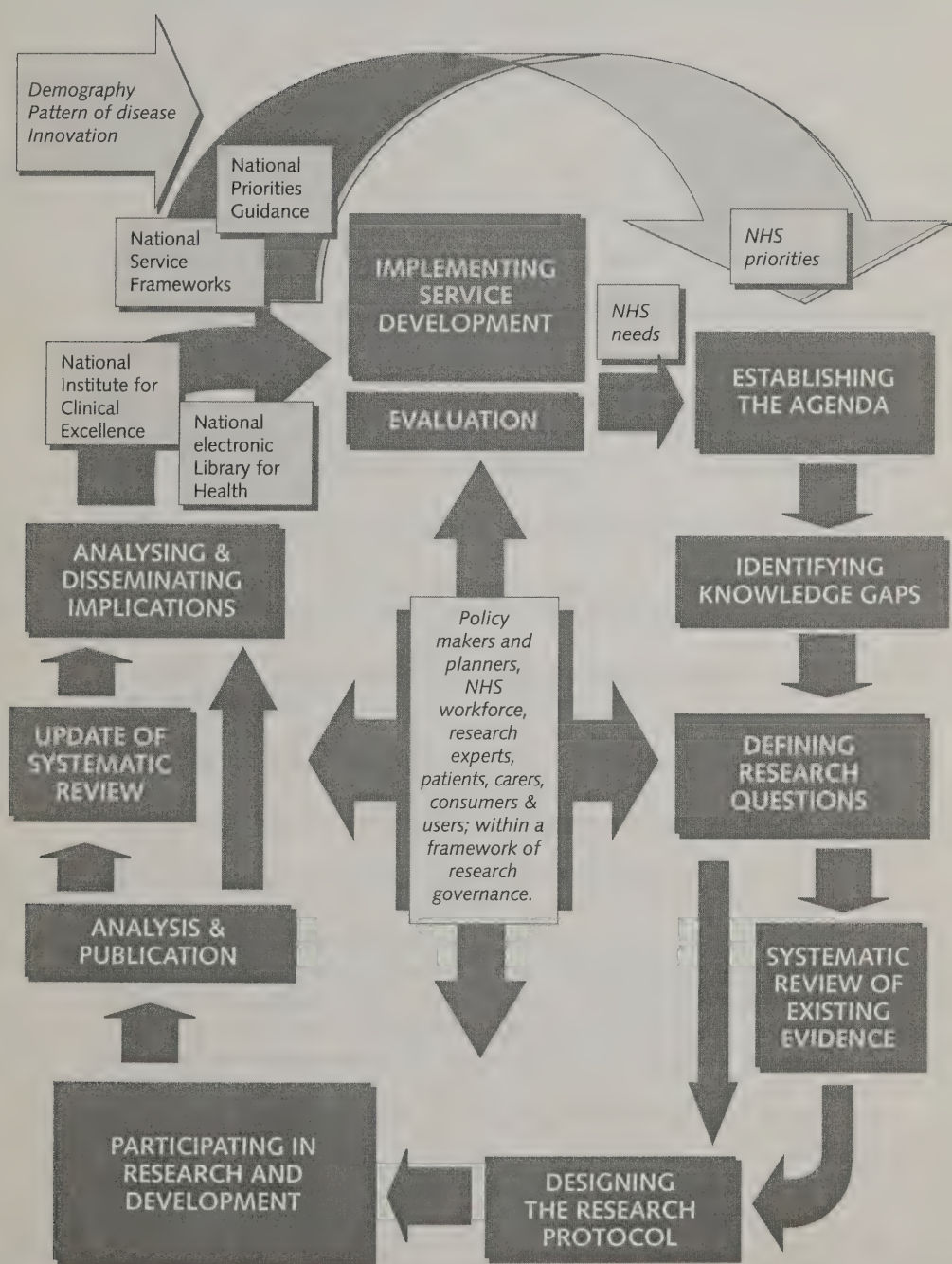
The costs of R&D in the NHS are split into three categories:

- **Research costs** are the costs of the R&D itself. They include the costs of data collection and analysis and other activities needed to answer the questions that a piece of R&D is addressing. They can include pay and indirect costs of staff employed to carry out the R&D.
- **Service Support Costs** are the additional patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the patient care service involved continued to be provided. This might cover items such as extra blood tests, extra in-patient days, extra nursing attention.
- **Treatment costs** are the patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given) the difference between the total Treatment Costs and the costs of the “standard alternative” (if any) can be termed the **Excess Element of Treatment Costs** (or just “**Excess Treatment Costs**”), but is nonetheless part of the Treatment Cost, not a service support or research cost.

Service support costs and, where appropriate, research costs are met from NHS R&D Funding. Treatment costs are normally met through commissioning arrangements for patient care. A detailed statement of policy, including arrangements for R&D with exceptionally high excess treatment costs, can be found on the R&D pages of the Department of Health's website.



# Health R&D, policy and practice







# Establishing the new funding systems: key steps

## 2000

March	<p>Ministerial announcement about future of NHS R&amp;D Funding.</p> <p>DH publishes Research and Development for a First Class Service on DH website, together with report of the Strategic Review of the NHS R&amp;D Levy.</p> <p>DH establishes steering arrangements for analyses of NHS activities and costs associated with a range of externally funded R&amp;D in a number of NHS bodies. These studies will be conducted jointly with the NHS and external funders, and will involve wide consultation and discussion.</p>
April	<p>DH publishes for consultation draft proposals for the future operation of NHS Support for Science.</p> <p>DH starts discussions with Health Authorities on the best way of integrating their current funding for R&amp;D and R&amp;D capacity with the new funding systems.</p>
June	<p>DH publishes for consultation draft proposals for the future operation of NHS Priorities and Needs R&amp;D Funding.</p>
July	<p>DH provides indicative allocations for 2001/2002 to existing contract holders.</p> <p>NHS bodies provide information about eligible external R&amp;D grants that drive their NHS costs.</p>
October	<p>DH publishes details of the future operation of NHS Support for Science.</p> <p>DH discusses with NHS bodies estimates of the proportion of each body's indicative allocation of NHS R&amp;D Funding that will in future be managed within NHS Support for Science, with the remainder to be managed within NHS Priorities and Needs R&amp;D Funding. These estimates will be derived from information provided by the bodies concerned about external grants driving NHS costs, and information from the analyses of NHS activities and costs started in March 2000.</p> <p>DH announces allocations for 2001/2002 from the R&amp;D Modernisation Fund.</p>



- December DH announces R&D allocations for 2001/2002, broken down for each recipient into NHS Support for Science and NHS Priorities and Needs R&D Funding.
- DH announces indicative R&D allocations for 2002/2003.
- DH publishes details of the operation of NHS Priorities and Needs R&D Funding, and notifies NHS bodies of the information required from them in March 2001 in preparation for its introduction.
- DH announces the priorities and goals to be addressed by the R&D Modernisation Fund in 2002/2003.

## 2001

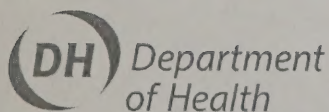
- March NHS bodies provide information on all R&D work whose costs are not met by their allocation from NHS Support for Science, indicating how they propose this work should be managed within the NHS Priorities and Needs R&D Funding system, and ways in which they might respond to the priorities for the R&D Modernisation Fund in 2002/2003.
- Summer DH announces how all work within NHS Priorities and Needs R&D Funding, including that currently funded through the NHS R&D Programme, will in future be grouped, managed and reviewed over a five year cycle.
- DH establishes initial reviews within this cycle, to report by the end of 2001.
- October DH announces allocations for 2002/2003 from the R&D Modernisation Fund.
- December Confirmation of allocations for 2002/2003.

## 2002

- February DH announces allocations of NHS Priorities and Needs R&D Funding for 2003/2004.







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